

AMENDMENTS

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of claims:

1. (currently amended) A method of forecasting a pharmacokinetic parameter of a lipid A analog as an aggregate structure in solution or in an injection preparation, wherein said aggregate structure in solution or injection preparation contains a lipid A analog or a pharmacologically acceptable salt thereof, said method comprising

measuring at least one of membrane fluidity and circular dichroism of the solution or the injection preparation;

preparing a plurality of lots of solutions, each solution having a unique, known value of said pharmacokinetic parameter;

measuring the membrane fluidity or circular dichroism of said plurality of lots of solutions;

preparing a graphical correlation for a said plurality of tested lots of solutions, said correlation being between the at least one of membrane fluidity and circular dichroism and said pharmacokinetic parameter;

using the measuring of the at least one of membrane fluidity or and circular dichroism as well as the graphical correlation to forecast the and said unique, known value of said

pharmacokinetic parameter ~~of the solution or the injection~~
~~preparation.~~

2. (canceled).

3. (currently amended) The method according to claim 1,
wherein quality evaluation is conducted in order to obtain an
injection preparation exhibiting a constant ~~pharmacokinetic~~
pharmacokinetic parameter.

4. (previously presented) The method according to claim 1,
which is conducted during preparation of the injection
preparation.

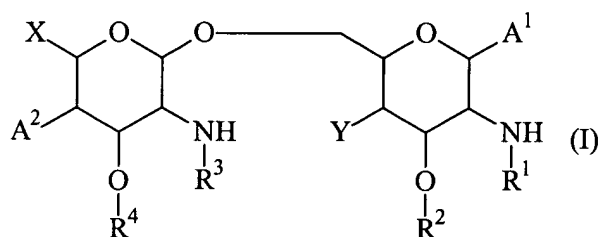
5. (previously presented) The method according to claim 1,
wherein the membrane fluidity is measured by a fluorescence
probe method which uses, as parameters, at least one of order
parameter (S), fluorescence polarity (P) and fluorescence
anisotropy (r).

6. (previously presented) The method according to claim 1,
wherein the injection preparation further contains aggregates
having a diameter not greater than 30 nm, and is prepared by
dissolving the lipid A analog or a pharmacologically acceptable

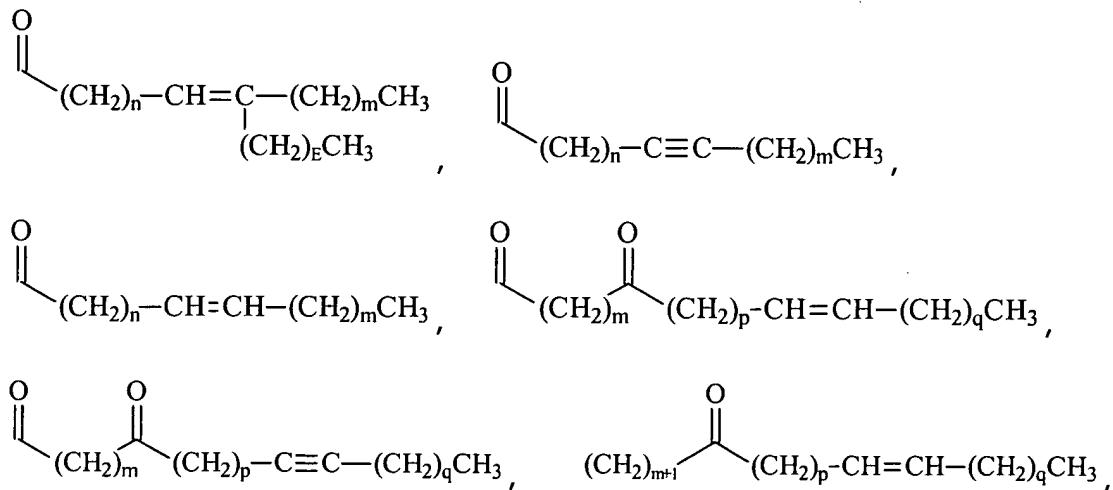
salt thereof in an alkaline aqueous solution and then adding a buffer thereto.

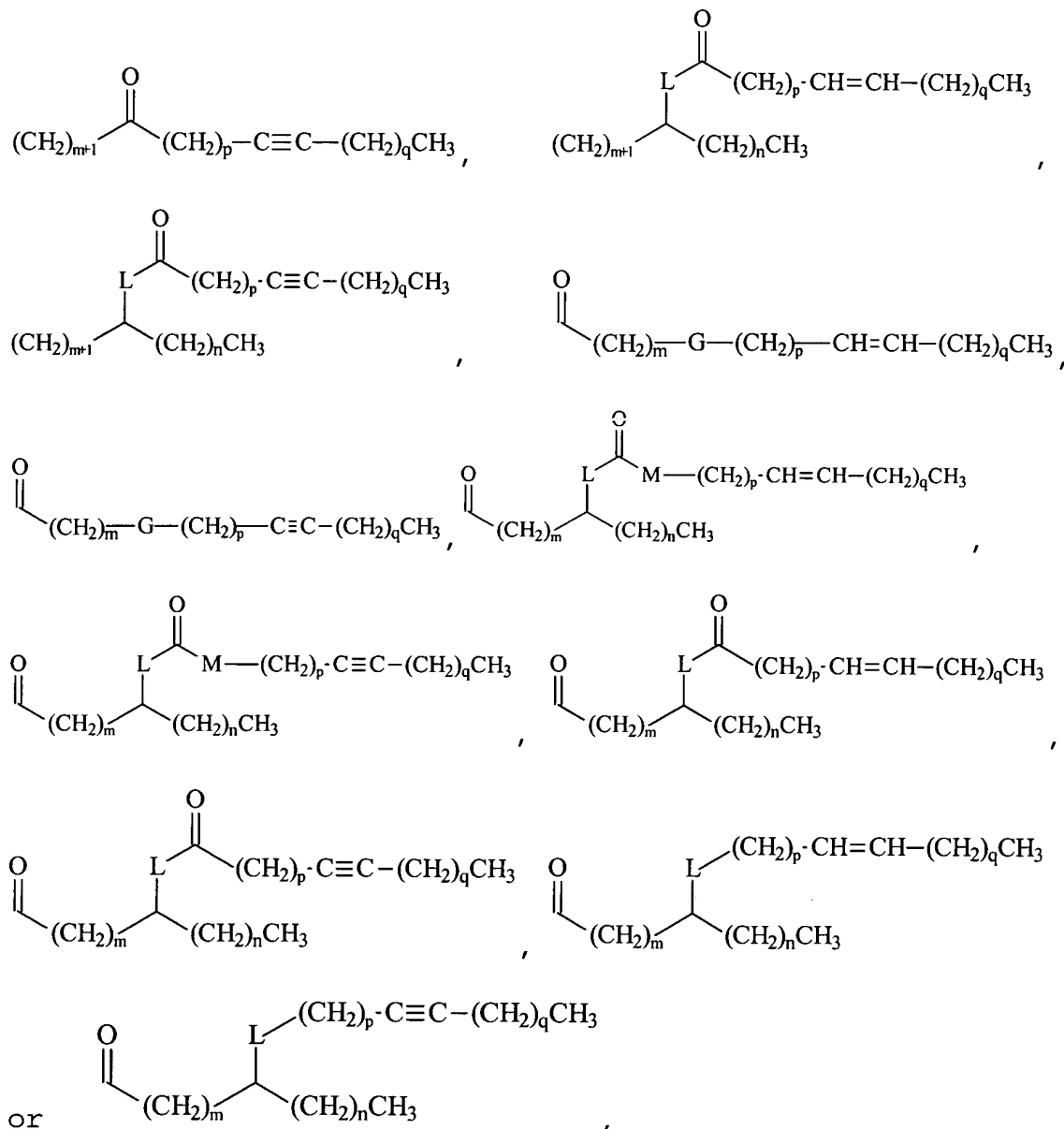
7. (previously presented) The method according to claim 1, wherein the injection preparation is an aqueous injection or freeze-dried preparation.

8. (previously presented) The method according to claim 1, wherein the lipid A analog or a pharmacologically acceptable salt thereof is a compound represented by the following formula (I):



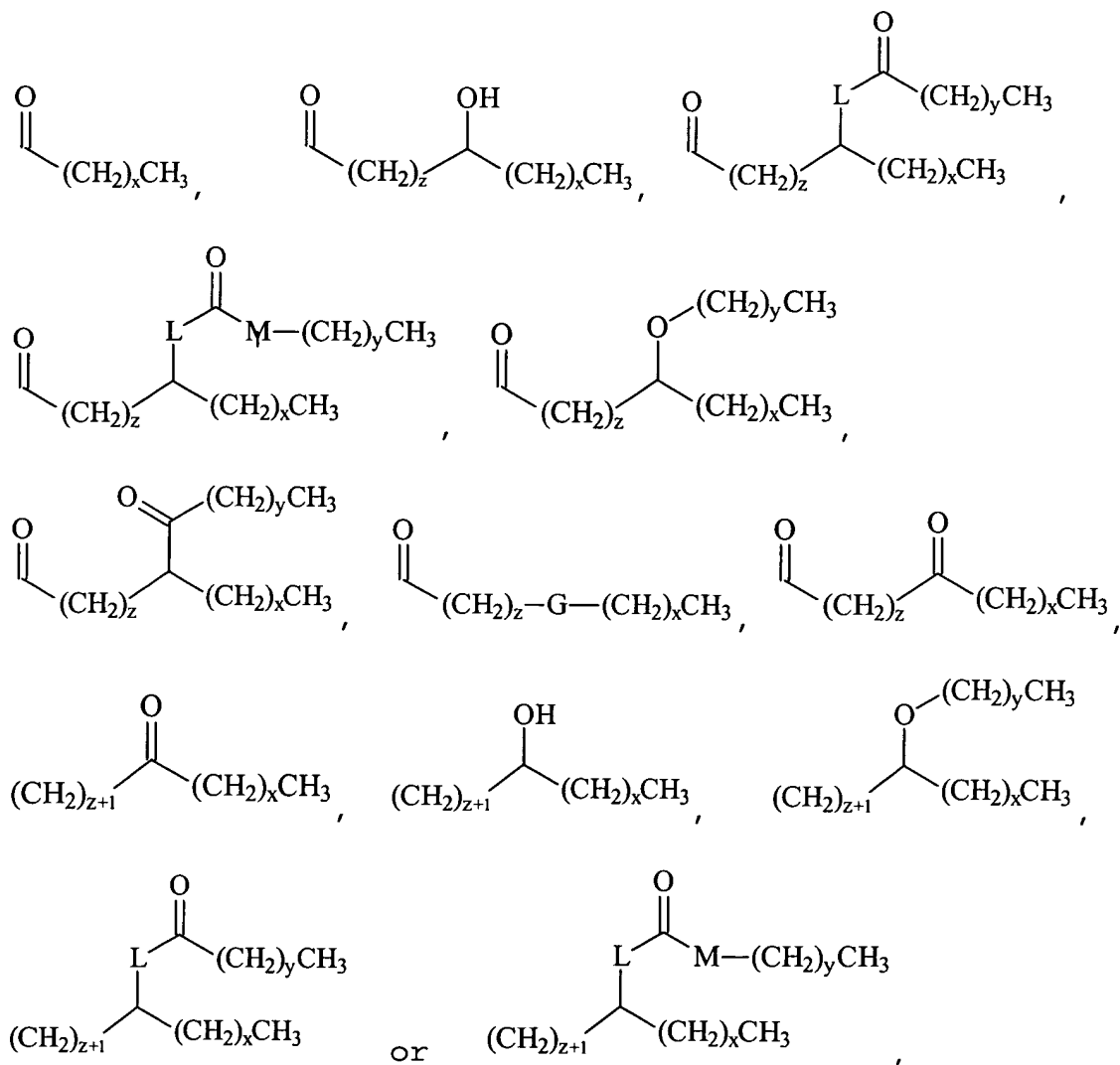
wherein at least one of R^1 , R^2 , R^3 and R^4 is



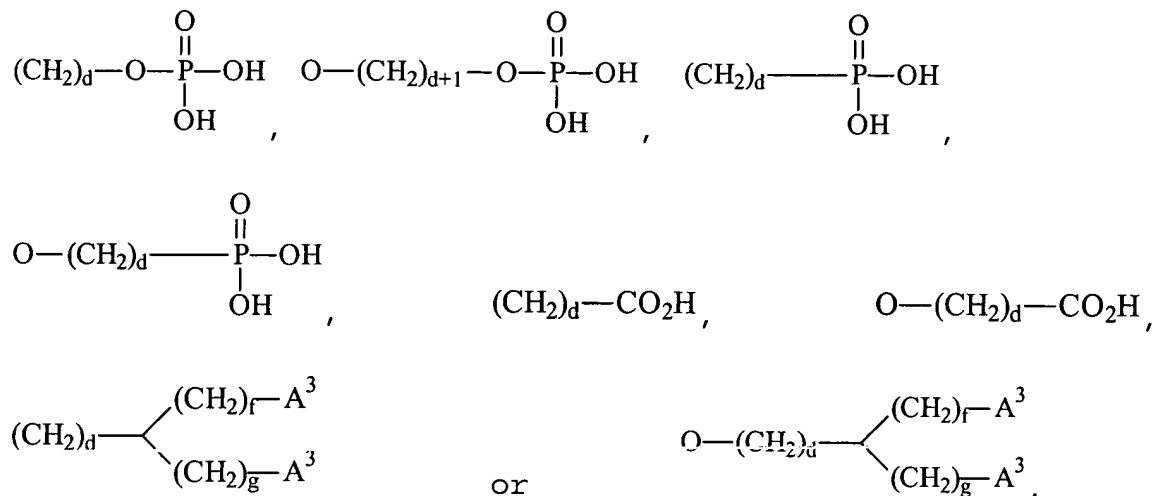


wherein each L is O, N or C; each M is O or N; each E independently is an integer of 0 to 14; each G independently is N, O, S, SO or SO₂; each m independently is an integer of 0 to 14; each n independently is an integer of 0 to 14; each p independently is an integer of 0 to 10; each q independently is an integer of 0 to 10,

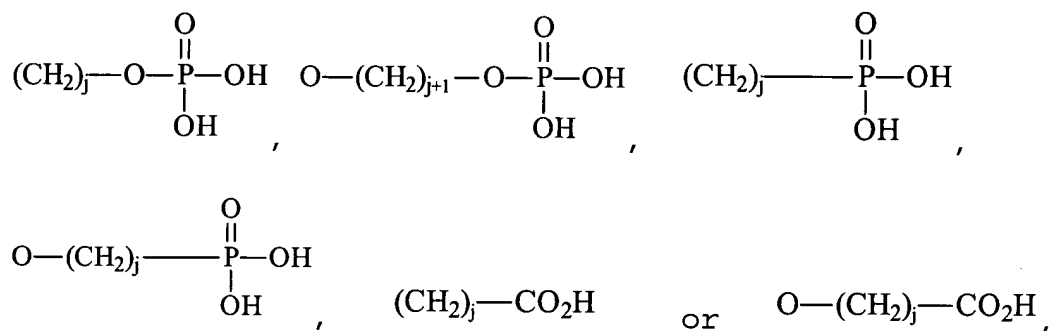
the rest of R^1 , R^2 , R^3 and R^4 are, independently of one another,



wherein each L is O, N or C; each M is O or N; each x independently is an integer of 0 to 14; each y independently is an integer of 0 to 14; each z independently is an integer of 0 to 10; each G independently is N, O, S, SO or SO₂,
 A^1 and A^2 are, independently of one another, H, OH, OCH₃,

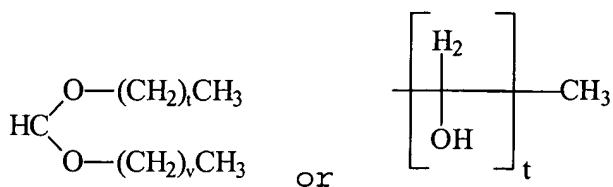


wherein each d independently is an integer of 0 to 5; each f independently is an integer of 0 to 5; each g independently is an integer of 0 to 5; each A³ independently is



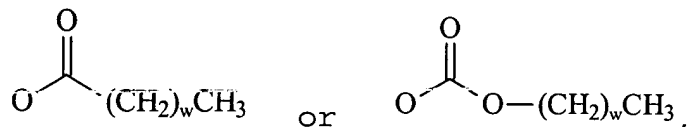
wherein each j independently is an integer of 0 to 14,

X is H, (CH₂)_tCH₃, (CH₂)_tOH, (CH₂)_tO(CH₂)_vCH₃, (CH₂)_tOPO(OH)₂,
 (CH₂)_t-CH=CH-(CH₂)_vCH₃, (CH₂)_t-O-R⁵,



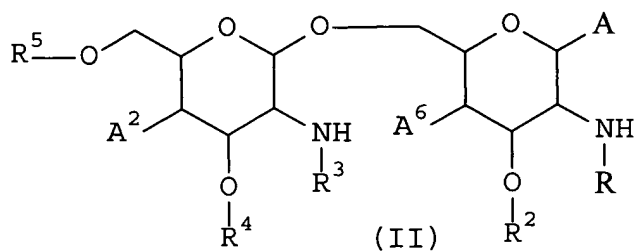
wherein t and v , are independently of one another, an integer of 0 to 14; R^5 is any of the above definitions of R^1 to R^4 ,

Y is H, OH, $O(CH_2)_wCH_3$, a halogen atom,

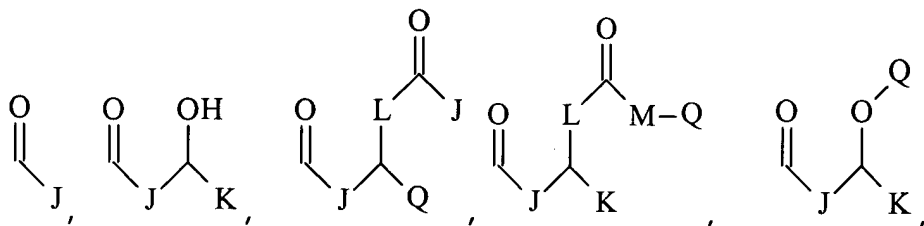


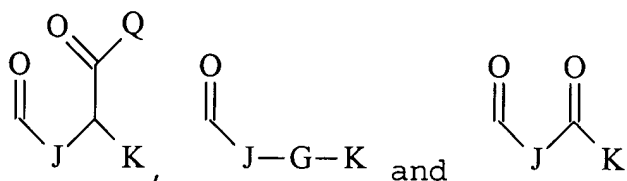
wherein w is an integer of 0 to 14,
or a pharmacologically acceptable salt thereof.

9. (previously presented) The method according to claim 1, wherein the lipid A analog is a compound represented by the following formula (II):

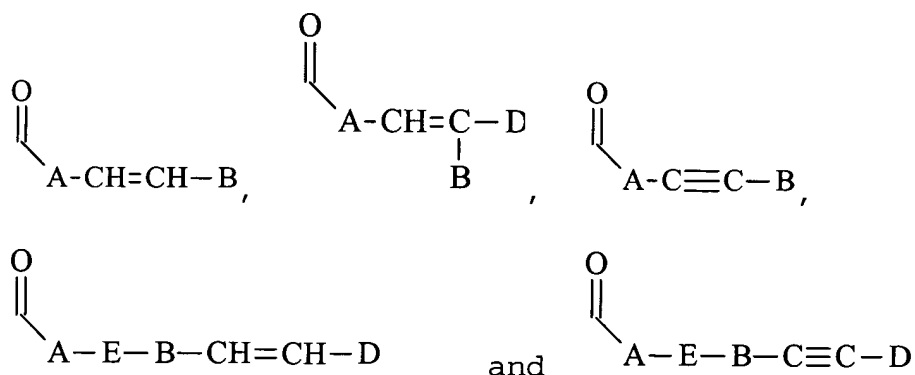


wherein R^1 is a group selected from the groups consisting of

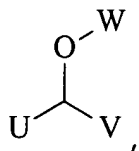




wherein J, K and Q are each a linear or branched alkyl group of 1 to 15 carbon atoms; L is O, NH₂ or CH₂; M is O or NH; G is NH, O, S, SO or SO₂, R² is a linear or branched alkyl group of 5 to 15 carbon atoms, R³ is a group selected from the groups consisting of



wherein E is N, O, S, SO or SO₂; A, B and D are each a linear or branched alkyl group of 1 to 15 carbon atoms, R⁴ is a group selected from the groups consisting of a linear or branched alkyl group of 4 to 20 carbon atoms and



wherein U and V are each a linear or branched alkyl group of 2 to 15 carbon atoms; W is a hydrogen atom or a linear or

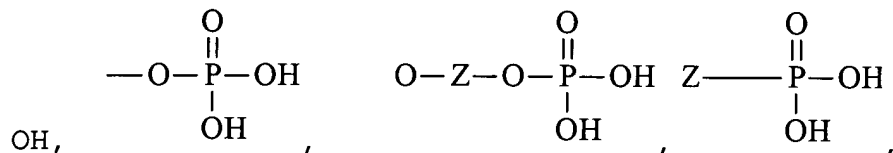
branched alkyl group of 1 to 5 carbon atoms,

R⁵ is a group selected from the groups consisting of a hydrogen atom, J', -J'-OH, -J'-O-K', -J'-O-K'-OH and

-J'-O-PO(OH)₂, wherein J' and K' are each a linear or branched alkyl group of 1 to 5 carbon atoms,

R⁶ is a group selected from the groups consisting of a hydroxyl group, a halogen atom, an alkoxy group of 1 to 5 carbon atoms, and an acyloxy group of 1 to 5 carbon atoms,

A¹ and A² independently are each a group selected from the groups consisting of

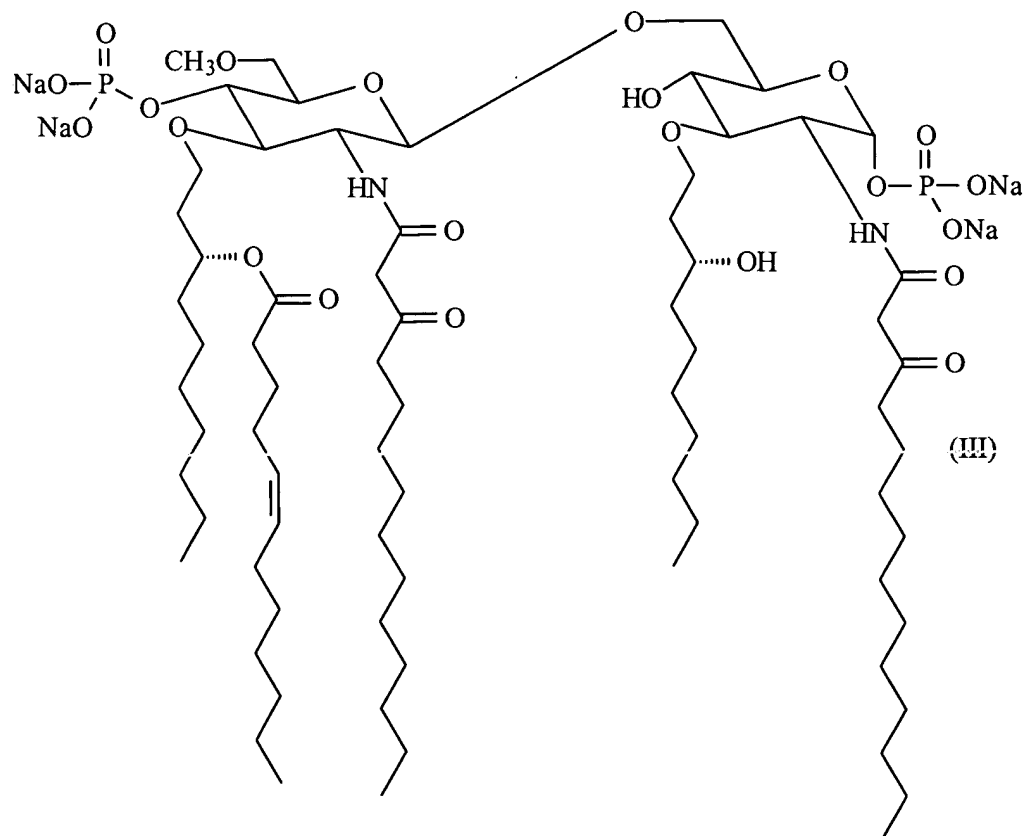


and $\text{O}-\text{Z}-\text{CO}_2\text{H}$,

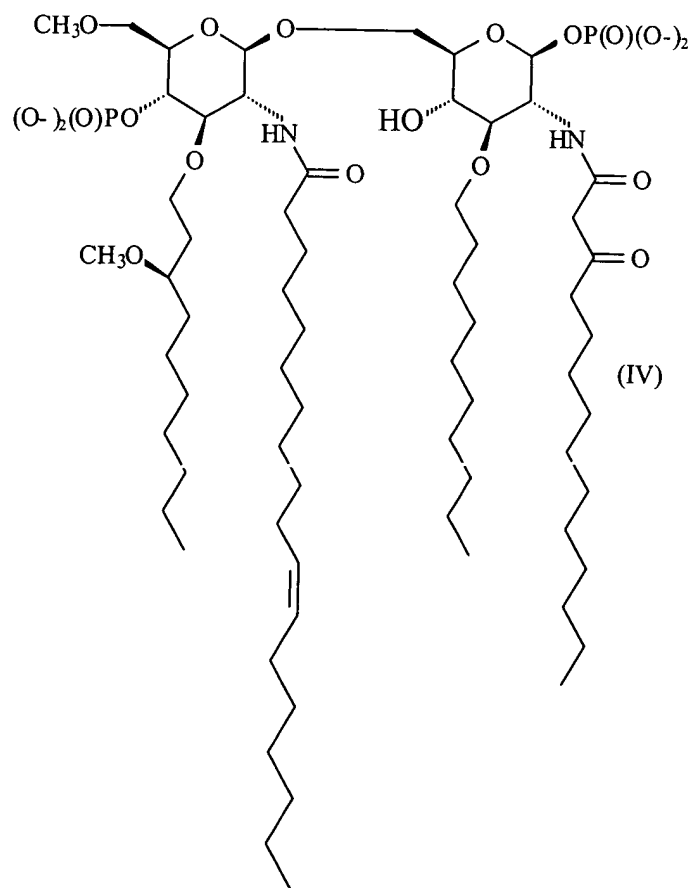
wherein Z is a linear or branched alkyl group of 1 to 10 carbon atoms,

or a pharmacologically acceptable salt thereof.

10. (previously presented) The method according to claim 1, wherein the lipid A analog is a compound represented by the following formula (III):



11. (previously presented) The method according to claim 1,
wherein the lipid A analog is a compound represented by the
following formula (IV):



12. (previously presented) The method according to claim 1, wherein the lipid A analog or a pharmacologically acceptable salt thereof has an aggregate structure in endoplasmic reticulum of lipid biomolecular membrane or micelle.